

### REMARKS

The foregoing amendment cancels claims 10 and 24. Cancellation of these claims are being made without prejudice to Applicants' right to reassert, in a continuing application, the subject matter of said claims.

### Claims in this Application

There appears to be some discrepancy between Applicants' records and the PTO records as regards to the claims now in this application. According to Applicants' records, the claims are numbers 1-3, 5-8, 11-17, 19-21 and 34-37. These are the claims which are set forth, in clean form, on the foregoing pages 2-7. Claims 7, 8 and 11-17 have been withdrawn from consideration as being directed to a non-elective invention. However, they remain in the application. Furthermore, they were included in now-terminated Interference No. 104,264 as claims corresponding to the count. Attached hereto is a copy of an Interference Initial Memorandum (Form 850) dated 19 November 1998 which lists claims 7, 8 and 11-17 as patentable claims corresponding to the [proposed] count. It is submitted that these claims do not cover an invention which would be separately patentable from the other remaining claims in this application and that, therefore, they should be included in the proposed interference, for which papers under Rules 607 and 608(a) have been submitted.

The Office Action herein responded to refers to claim 18. However, this claim was cancelled in an amendment filed on 19 November 1998. Attached is a copy of said amendment.

### Obviousness-Type Double Patenting Rejections

The Examiner has rejected all of the claims in this application on the basis of obviousness-type double patenting over 28 patents. These patents are all owned by Applicants' assignee and, therefore, these double patenting rejections can be overcome by submitting appropriate terminal disclaimers.

Some of these double patenting rejections are proper and Applicants are submitting herewith an appropriate Terminal Disclaimer. However, as to some of the patents over which

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double patenting rejections have been made, it is Applicants' contention that there is no obviousness situation and therefore, as to these patents, reconsideration is respectfully requested.

The cited patents will be discussed in the order raised by the Examiner.

U.S. Patent No. 5,225,180. All of the claims in the instant <sup>reference</sup>~~application~~ are directed to a reagent for preparing a radiolabelled peptide, the reagent comprising a plurality of amino acid residues in which the reagent is directly labelled with technetium 99m. All of Applicants' claims require a covalent linkage between the specific binding compound and the radiolabel complexing moiety.

As explained in the '180 specification:

This method of directly labeling somatostatin or somatostatin derivatives, analogues or related peptides is advantageous over the methods known in prior art. Methods of radioactively labeling somatostatin or related peptides known prior to the present invention required the use of substituted somatostatin derivatives that were comprised of at least one tyrosine residue in order to permit radioiodination of the peptide. Alternatively, radiolabelled somatostatin peptides have been made by covalent linkage of a metal chelating group to the amino terminus of the peptide and reaction with the radionuclide. A particular disadvantage of the covalent attachment of these chelating groups is that the presence of these groups at the amino terminus of the peptide might interfere with the biological properties of the peptides in vivo and in addition may intrinsically cause biocompatibility problems either itself or when linked to another peptide.

6:51-68: It is therefore believed that this double patenting rejection should be withdrawn.

U.S. Patent No. 6,107,459. Included in the Terminal Disclaimer.

U.S. Patent No. 5,552,525. Included in the Terminal Disclaimer.

U.S. Patent No. 6,019,958. Included in the Terminal Disclaimer.

U.S. Patent No. 5,811,394. The rejection is respectfully traversed. All of the claims in this <sup>reference</sup>~~application~~ require that the technetium binding moiety comprise two protected cysteine residues.

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In Applicants' claims, the corresponding radiolabel complexing moiety must comprise a residue having only a single thiol group, and therefore there cannot be two cysteines.

U.S. Patent No. 5,736,122. Included in the Terminal Disclaimer.

U.S. Patent No. 5,807,538. Included in the Terminal Disclaimer.

U.S. Patent No. 5,807,537. Included in the Terminal Disclaimer.

U.S. Patent No. 5,780,007. Included in the Terminal Disclaimer.

U.S. Patent No. 5,788,960. This rejection is respectfully traversed. The claimed scintigraphic imaging agents in the reference require the presence of a technetium binding moiety having two cysteine residues. Applicant's claims are limited to imaging agents in which the radiolabel complexing moiety has only a single thiol group and therefore there cannot be two cysteines.

U.S. Patent No. 6,074,627. Included in the Terminal Disclaimer.

U.S. Patent No. 5,997,845. Included in the Terminal Disclaimer.

U.S. Patent No. 6,086,849. Included in the Terminal Disclaimer.

U.S. Patent No. 5,997,844. Included in the Terminal Disclaimer.

U.S. Patent No. 5,866,097. Included in the Terminal Disclaimer.

U.S. Patent No. 5,989,519. Included in the Terminal Disclaimer.

U.S. Patent No. 5,968,476. Included in the Terminal Disclaimer.

U.S. Patent No. 5,965,107. Included in the Terminal Disclaimer.

U.S. Patent No. 5,849,260. This rejection is respectfully traversed. Claims 1-5 and 8-12 of this reference cover a reagent which comprises a specific binding peptide covalently linked to a technetium-99m binding moiety in which the binding moiety must contain two protected cysteine groups. In Applicants' claims, the radiolabel complexing moiety has only a single thiol group and therefore there cannot be two cysteines.

U.S. Patent No. 5,879,658. Included in the Terminal Disclaimer.

U.S. Patent No. 5,888,474. Included in the Terminal Disclaimer.

U.S. Patent No. 6,017,510. Included in the Terminal Disclaimer.

U.S. Patent No. 5,654,272. This rejection is respectfully traversed. All of the claims in this reference are directed to a scintigraphic imaging agent bound to a technetium-99m binding moiety which has two protected cysteine groups. In Applicants' claims, the scintigraphic imaging agent has a radiolabel complexing moiety with only a single thiol group and therefore there cannot be two cysteines.

U.S. Patent No. 5,561,220. Included in the Terminal Disclaimer.

U.S. Patent No. 5,925,331. This rejection is respectfully traversed. Claims 1-29 and 34-39 of the reference are directed to a reagent for preparing a scintigraphic imaging agent, the reagent comprising a specific binding compound covalently linked to a technetium-99m binding moiety which has two protected cysteine groups. In Applicants' claims, the radiolabel complexing moiety has only a single thiol group and therefore there cannot be two cysteines.

U.S. Patent No. 5,508,020.

This rejection is respectfully traversed. The claims in the referenced patent are concerned with a scintigraphic imaging agent comprising a multiplicity of specific binding peptides, which are covalently linked to a technetium binding moiety. The scintigraphic imaging agents claimed by Applicants do not cover a multiplicity of specific binding peptides.

U.S. Patent No. 5,951,964. This rejection is respectfully traversed. Claims 1-16, 24-28 and 30 of the reference patent are concerned with a scintigraphic imaging agent comprising at least two specific binding peptides, covalently linked to a technetium binding moiety. The scintigraphic imaging agent claimed by Applicants has only a single specific binding peptide.

U.S. Patent No. 5,443,815. Included in the Terminal Disclaimer.

CONCLUSION

In view of the foregoing amendment, these remarks and the attached Terminal Disclaimer, it is believed that all of the claims now in this application are allowable and that they are in condition to be put into interference with U.S. Patent No. 5,759,516.

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If the Examiner is of the opinion that terminal disclaimers are required for any of the patents where the rejections have been traversed, it is requested that she discuss this matter by telephone with the undersigned.

Respectfully submitted,

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